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Docket No: 05432/100M029-US2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/750,049

Art Unit: Not Yet Assigned

Applicant : Hans PETERSEN et al.

Filed : December 30, 2003

Examiner: Not Yet Assigned

Title : CRYSTALLINE BASE OF CITALOPRAM

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In order to comply with 37 C.F.R. §§ 1.97 and 1.98, attached hereto  
is a copy of Form PTO/SB/08. Copies of the documents listed thereon were  
previously submitted during prosecution of the parent application, Serial No.  
10/245,824, filed September 12, 2002.

In accordance with MPEP Sections 609 and 707.05(b), it is requested  
that each document cited (including any cited in applicant's specification which is  
not repeated on the attached PTO/SB/08) be given thorough consideration and that

it be cited of record in the prosecution history of the present application by initialing Form PTO/SB/08 next to the document. Such initialing is requested even if the Examiner does not consider a cited document to be sufficiently pertinent to use in a rejection, or otherwise does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application.

This Information Disclosure Statement is filed pursuant to 37 C.F.R. § 1.97(b)(3), before the mailing of a first Office Action on the merits. Accordingly, it is believed that no fee is due. The Commissioner is authorized to charge any additional fees required in connection with this Information Disclosure Statement or credit any overpayment to Deposit Account No. 04-0100.

The present Information Disclosure Statement is being submitted in compliance with 37 C.F.R. § 1.56, but the citation of such documents is not to be construed as an admission that such documents are necessarily relevant or prior art. No representation is intended that the cited documents represent the results of a complete search, and it is anticipated that the Examiner, in the normal course of examination, will make an independent search and will determine the best prior art consistent with 37 C.F.R. § 1.104(a) and in the course of each search, will review for relevance every document cited on the attached form even if not initialed.

Early and favorable consideration is earnestly solicited.

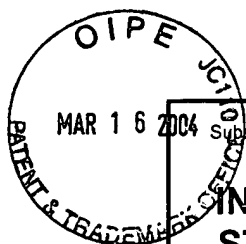
Respectfully submitted,

Dated: March 16, 2004

By: 

Jay P. Lessler  
Reg. No. 41,151  
Attorney for Applicants

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PTO/SB/08a/b (08-03)

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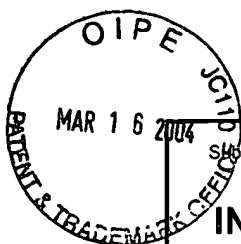
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/750,049
				Filing Date	December 30, 2003
				First Named Inventor	Hans Petersen
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	1	of	7	Attorney Docket Number	05432/100M029-US2

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	1.	2002/0061925	05-23-2002	Petersen et al.	
	2.	2001/0049450	12-06-2001	Ikemoto et al.	
	3.	5,523,423	06-04-1996	Murthy et al.	
	4.	Re 34,712	08-30-1994	Boegesoe et al.	
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	6.	4,943,590	07-24-1990	Boegesoe et al.	
	7.	4,672,133	06-09-1987	Crookes	
	8.	4,650,884	03-17-1987	Bogeso	
	9.	4,535,186	08-13-1985	Husbands et al.	
	10.	4,314,081	02-02-1982	Molloy et al.	
	11.	4,136,193	01-23-1979	Bøgesø et al.	
	12.	3,467,675	09-16-1969	Petersen et al.	
	13.	2,584,429	02-05-1952	Croxall et al.	
	14.	2,233,970	03-04-1941	Andersag et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	15.	WO 03/007872	01-30-2003	Sathyanarayana et al.		
	16.	GB 2375763	11-27-2002	Matrix Laboratories Limited		
	17.	WO 02/072565	09-19-2002	Biswas et al.		
	18.	WO 02070501	09-12-2002	Cipla Ltd.		
	19.	EP 1169314	09-04-2002	H. Lundbeck A/S		
	20.	DK 173903	02-11-2002	H. Lundbeck A/S		
	21.	NL 1017413	11-01-2001	H. Lundbeck A/S		
	22.	DE 10108042 A1	10-18-2001	H. Lundbeck A/S		
	23.	WO 0168627	09-20-2001	H. Lundbeck A/S		
	24.	EP 1125907	08-22-2001	Sumika Fine Chemicals Co.		
	25.	WO 0122941	04-05-2001	H. Lundbeck A/S		
	26.	IT MI99A001486	01-22-2001	VIS Farmaceutici S.P.A.		
	27.	WO 01/02383 A2	01-11-2001	VIS Farmaceutici S.P.A.		
	28.	WO 01/02383 A3	10-18-2001	Lundbeck Pharmaceuticals Italy S.P.A.		
	29.	NL 1016435	11-06-2000	H. Lundbeck A/S		

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				First Named Inventor	Hans Petersen
				Art Unit	Not Yet Assigned
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Sheet	2	of	7	Attorney Docket Number	05432/100M029-US2

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31.	WO 00/23431	04-27-2000	H. Lundbeck A/S		
32.	PCT/DK00/00183	04-13-2000	H. Lundbeck A/S		
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46.	EP 0 171 943	11-17-1988	H. Lundbeck & Co. AS		
47.	DE 26 57 013	07-28-1977	Kefalas AS		
48.	FI 63754	07-15-1977	Kefalas A/S		

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
	49.	Kirk-Othmer, <i>Encyclopedia of Chemical Technology</i> , Second Edition, Volume 6: 482, New York: John Wiley & Sons (1965)			
	50.	Kunsemuller, Johannes, Ed., <i>Meyers Lexikon der Technik und der exakten Naturwissenschaften</i> : 1151, Mannheim/Wien/Zurich: Bibliographisches Institute (1970)			
	51.	Bates, Robert B., et al., Ed., <i>Research Techniques in Organic Chemistry</i> : 50-52, Englewood Cliffs, NJ: Prentice-Hall, Inc. (1971)			
	52.	<i>Organikum: Organisch-Chemisches Grundpraktikum</i> : pp. 39-41, Veb Deutscher Verlag Der Wissenschaften, Berlin (1974)			
	53.	Hyttel, John, "Citalopram - Pharmacological Profile of a Specific Serotonin Uptake Inhibitor with Antidepressant Activity," <i>Prog. Neuro-Psychopharmacol &amp; Biol. Psychiat.</i> 6: 277-295 (1982)			
	54.	Gravem, A., et al., "A double-blind comparison of citalopram (Lu 10-171) and amitriptyline in depressed patients," <i>Acta Psychiatr. Scand.</i> 75: 478-486 (1987)			
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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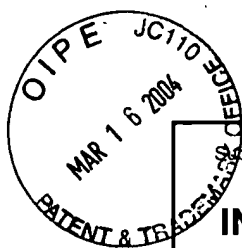
Sheet **3** of **7****Complete if Known**

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57.	Kirk-Othmer, <i>Encyclopedia of Chemical Technology</i> , Fourth Edition, Volume 7: 683-5, New York: John Wiley & Sons (1993)	
58.	(2001) Patenters beskyttelsesomfang, pp. 366-388, 403-420.	
59.	(1999) Patentrett, pp. 70-71.	
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61.	(1992) Becher J., "OmkrySTALLISATION", <i>Organic Synthese</i> , pp. 90-94.	
62.	(1991) Collins English Dictionary, 3rd edition, p. 1224.	
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64.	(1965) <i>Encyclopedia of Chemical Technology</i> , Second Edition, New York, John Wiley & sons, vol. 6, p. 482.	
65.	(1964) <i>Organisk Kemisk Syntese</i> , pp. 586-592.	
66.	(1958) <i>Methoden der Organischen Chemie</i> , pp. 345-346.	
67.	Academic Press Dictionary of Science and Technology, "precipitation"	
68.	Vogel's Textbook of Quantitative Chemical Analysis, p. 225.	
69.	"Krystallisation", <i>Teknisk Leksikon IV</i> , pp. 399-400.	
70.	The Merck Index, 12th edition, pp. 361, 1695.	
71.	Hendrickson et al., <i>Organic Chemistry</i> , 3rd edition, McGraw-Hill Company, pp. 9-10.	
72.	Grom HPLC 2000.	
73.	Bull E., "Lundbeck kan tjene mia. Pa genistreg", <i>Borsen</i>	
74.	Notice of Opposition filed on behalf of: Biochemie GmbH (with English Translation)	
75.	Notice of Opposition filed on behalf of: neuraxpharm Arzneimittel GmbH & Co. KG, dated 9/5/02	
76.	Notice of Opposition filed on behalf of: neuraphram Arzneimittel GmbH & Co. KG, dated 5/22/03 (with English Translation)	
77.	Notice of Opposition filed on behalf of: Stada-Arzneimittel Aktiengesellschaft (with English Translation)	
78.	Notice of Opposition filed on behalf of: RATIOPHARM GMBH	
79.	Notice of Opposition filed on behalf of: hexal Pharma GmbH	
80.	Notice of Opposition filed on behalf of: Tiefenbacher Alfred E.Gmb & Co.	
81.	Notice of Opposition filed on behalf of: Biomo PharmaGmbH	
82.	Notice of Opposition filed on behalf of: Egis Gyogyszerigyar RT, dated 5/22/03	
83.	Notice of Opposition filed on behalf of: Merck dura GmbH (with English Translation)	
84.	Notice of Opposition filed on behalf of: Niche Generics Limited	
85.	(1996) D. Haupt, J. Chromatogr. B, 685:299-305.	
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89.	(1972) M. Lj. Mihailovic et al., <i>Journal of Chemical Society, Perkin Transaction I</i> , pp. 2460-2464.	
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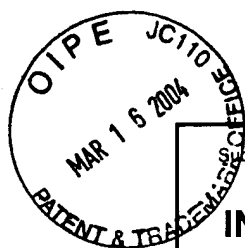
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Sheet	4	of	7		

92.	The Design of Organic Syntheses, S. Turner, Stereospecific Control Elements - Resolution - Asymmetric Synthesis, pp. 112-139) published in or about 1976).	
93.	Topics in Stereochemistry, vol. 6 (eds. N.L. Allinger & E.L. Eliel), S.H. Wilen, Resolving Agents and Resolutions in Organic Chemistry, pp. 107-176 (published in or about 1971).	
94.	Declaration of Dr. C. Satyanarayana, Manufacturing Process for Citalopram Hydrobromide	
95.	Statement of Peter Somfai, Professor, dated 02/05/03	
96.	Declaration of Karl Anker Jorgensen, dated 05/03/02	
97.	Opinion of Torbjorn Norin, dated 05/03/02	
98.	Declaration of Karl Anker Jorgensen, dated 07/10/03	
99.	Kankan, R.N., Cipla Manufacturing & Research Division, Test results of Example 3 in EP 0347066, dated 03/08/02	
100.	Kankan, R.N., Cipla Manufacturing & Research Division, Citalopram-methylester results, dated 5/29/02	
101.	Third party observation in accordance with Art. 115 EPC regarding European Patent Application No. EP01 909 568.6-2117, in the name of H. Lundbeck A/S; Maiwald Patentanwalts GmbH	
102.	Supplemental Declaration of Karl Anker Jorgensen, dated 07/10/03	
103.	Report, Dr. U. Riederer- Cyanation of 5-Bromocitalopram by the "Matrix Method" - 21 and 22 October 2002	
104.	Vogel, A.I., A Textbook of Practical Organic Chemistry including Qualitative Organic Analysis, preface, pp. 122-129	
105.	Houben, Dr. J., Die Methoden Der Organischen Chemie, Edwards Brothers, Inc., Ann Arbor, 1943, pp. 554-561	
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108.	Veibel, S., The Identification of Organic Compounds, 7th Ed., 1971, p. 1-2	
109.	Gattermann, L, Laboratory Methods of Organic Chemistry, Macmillian and Co., London, 1946, preface and pp. 3-8	
110.	Furniss, B. et al., Vogel's Textbook of Practical Organic Chemistry, 5th Ed. Longman Scientific & Technical, 1989, pp. 1-2, 135-143, 151-153	
111.	Casey, M. et al., Advanced Practical Organic Chemistry, Blackie, 1990, p. 155	
112.	Declaration of Hans Petersen	
113.	Declaration of Erik Fischer, Krystallisation af citaloprambase fra aprotiske oplosningmidler, dated 11/07/02	
114.	Declaration of Olov Sterner, Professor, dated June 10, 2002	
115.	Meyers Lexikon der Technik und der exakten Naturwissenschaften, page 1551	
116.	Jensen, K.A., Almen Kemi, 1969, pgs. 328-330	
117.	Declaration of Ejvind J. Christiansen, 10/25/02	
118.	Conclusions 4-11 of the President of the District Court of the Hague, M. Y. Bonneur, 4/12/02	
119.	Pleading Notes, Mr. Hendrick, District Court hearing, 3/22/02, ¶¶ 54-56	
120.	Witness Statement of Stanley Michael Roberts, June 2003	

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121.	HARWOOD et al., Experimental Organic Chemistry, 2d. ed., pp. 135-136 (1999)	
122.	Search results: CSD version 5.23 (April 2002) database, "citalpram3," 10/4/02	
123.	Deutsches Patent - und Markenamt, 4/3/02, DE 101 09 042.5-44	
124.	PRV, Awapatent, Underrattelse Enl §19 Patentlagen, 2012026, 3/20/02	
125.	Decision from Landgericht Munchen I, 10/9/02	
126.	Declaration of Prof. Dr. Herwig Schottenberger, 10/7/02	
127.	Statement of Peter Somfai, Professor, 7/4/02	
128.	Pleading Notes, District Court at The Hague, Case No. KG 02/179, 3/22/02	
129.	Grunden & Gozzo, Mal nr T 7589-02 Novartis Sverige AB / J. H. Lundbeck A/S, 5/31/02	
130.	Organisk Kemi Kth, Handledning Och Sakerhetsfreskrifter For Laborationskurserna I Organisk Kemi, pp. 21-26	
131.	Goran Zdansky, Handledning I Kemisk Laboratorieteknik (1975), pp. 21.2-21.5	
132.	Statement of Haleh Ahmadian re: Example 3 of EP 347066 (2/27/02)	
133.	Beyer & Walter, Handbook of Organic Chemistry, pp. 3-4 (1996)	
134.	Declaration of Philip A. Marshall, 8/24/03	
135.	District Court Decision, DE RECHTBANK TE'S-GRAVENHAGE, 12/23/02	
136.	Report by C. J. J. van Loon, dated 2/29/02	
137.	Declaration of R. N. Kankan, Cipla, 3/15/02	
138.	Vogel, Practical Organic Chemistry, 4 <sup>th</sup> ed., pp. 100-124 (1986)	
139.	Seventh Report of Dr. Robert Michael Adlington, 8/12/03	
140.	Exhibit "RMAM-7" To the 7th Report of Dr. Adlington: The Concise Oxford Dictionary, 7 <sup>th</sup> ed. (1982), pp. 79-80	
141.	Exhibit "RMAM-8" To the 7th Report of Dr. Adlington: Bob McDuell, A-Level Chemistry, Course Companion (1991) pp.45-47	
142.	Exhibit "RMAM-9" To the 7th Report of Dr. Adlington: Vogel's Textbook of Practical Organic Chemistry, 5 <sup>th</sup> ed. (1989), pp. v-vii, xvi-xix, xxi-xxiii, 131-144	
143.	Exhibit "RMAM-13" To the 7th Report of Dr. Adlington: "Calculation of the theoretical conversion of the Diol to Citalopram in Example 3 of '066 using 7.5ml of methanesulfonyl chloride, Conclusion: the MeSO <sub>2</sub> Cl is in excess (118.5%)"	
144.	Exhibit "RMAM-14" To the 7th Report of Dr. Adlington: "Calculation of the theoretical conversion of the Diol to Citalopram in Example 3 of '066 using 7.5ml of methanesulfonyl chloride, Conclusion: there is a 20% deficiency of MeSO <sub>2</sub> Cl (100-80=20)"	
145.	Exhibit "RMAM-15" To the 7th Report of Dr. Adlington: "Calculation of the yield on going from the Diol to Citalopram Hydrobromide in Example 3 of '066"	
146.	Exhibit "RMAM-16" To the 7th Report of Dr. Adlington: "Calculation of the % Yield on going from crystalline Citalopram free base to the hydrobromide salt in Example 3 of '066"	
147.	Exhibit "RMAM-17" To the 7th Report of Dr. Adlington: "Calculation of theoretical % Yields on going from the Diol to the hydrobromide salt in Example 3 of '066 with two amendments to the stated protocol"	
148.	Exhibit "RMAM-18" To the 7th Report of Dr. Adlington: "Explanation of the discrepancy in the amounts of starting materials used and yield of Citalopram oxalate stated in Example 1 of '926"	

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Examiner Signature		Date Considered	
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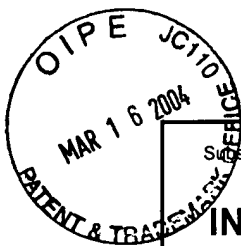
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Substitute for form 1449A/B/PTO				<b>Complete if Known</b>	
				Application Number	10/750,049
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				Filing Date	December 30, 2003
				First Named Inventor	Hans Petersen
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	6	of	7	Attorney Docket Number	05432/100M029-US2

149.	Exhibit "RMAM-19" To the 7th Report of Dr. Adlington: "Explanation of the discrepancy in the amount of sodium cyanide stated to have been used in Example 1 of '926"	
150.	Exhibit "RMAM-20" To the 7th Report of Dr. Adlington: "Calculation of the purity of the 1,1-di-(p-chlorophenyl)-4-dimethyl amino-1-butanol produced in Example 10 of Croxall"	
151.	Exhibit "RMAM-22" To the 7th Report of Dr. Adlington: Leo A. Paquette, Encyclopedia of Reagents for Organic Synthesis, Vol. 5, L-M (1995), preface, foreword, pp.3307-3312	
152.	Exhibit "RMAM-23" To the 7th Report of Dr. Adlington: Vogel's Textbook of Practical Organic Chemistry, 5 <sup>th</sup> ed. (1989), pp. 165-168	
153.	Exhibit "RMAM-29" To the 7th Report of Dr. Adlington: "Detailed Description of the Steps taken and Observations made During Lundbeck's Experiments" (June 2003)	
154.	Exhibit "RMAM-30" To the 7th Report of Dr. Adlington: "List of Chemicals"	
155.	Exhibit "RMAM-31" To the 7th Report of Dr. Adlington: "Photographs taken during the addition of Methanesulfonyl chloride"	
156.	Exhibit "RMAM-32" To the 7th Report of Dr. Adlington: "Photograph taken during equilibration with Ice Cooling"	
157.	Exhibit "RMAM-33" To the 7th Report of Dr. Adlington: Aldrich Handbook of Fine Chemicals and Laboratory Equipment (2003-2004), pp.617-619	
158.	Exhibit "RMAM-34" To the 7th Report of Dr. Adlington: "Photograph of Dr. Adlington wearing the items of clothing insisted on by Lundbeck"	
159.	Declaration of Trevor Laird, 3/6/02	
160.	Declaration of Hans Petersen, 5/6/02	
161.	Declaration of Dr. Ulrich Riederer, 1/8/03	
162.	Declaration of Dr. Ulrich Riederer, 1/14/03	
163.	Expert Report of Karl Anker Jørgensen, 8/18/03	
164.	Second Expert Report of Karl Anker Jørgensen, 9/20/03	
165.	Schedule A - Experiments (Annex to the 7th Report of Dr. Adlington)	
166.	Mortensen et al., <i>Journal of Neurochemistry</i> 79:237-247 (2001)	
167.	Ohman et al., <i>Journal of Chromatography B</i> 753:365-373 (2001)	
168.	Impurities in New Drug Substances Q3A(R), International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 2/7/02	
169.	Hansen et al., <i>European Journal of Pharmacology</i> 352:307-315 (1998)	
170.	Hansen et al., <i>The Journal for Pharmacology and Experimental Therapeutics</i> , 283:1333-1341 (1997)	
171.	Bigler et al., <i>European Journal of Med. Chem. - Chimica Therapeutica</i> Vol. 12, No. 3, pp. 289-295 (May-June 1997)	
172.	Kelliher et al., <i>Psychoneuroendocrinology</i> 28:332-347 (2003)	
173.	Third Report of Dr. Robert Michael Adlington	
174.	EPO Communication of 12 February 2002, Application No. 01 909 568.6-2117	
175.	Decision from Stockholm Tingsret dated 5 June 2002, PROTOKOLL	
176.	EPO Communication of 13 September 2002, Application No. 02 009 350.6-2117	

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Sheet	7	of	7	Attorney Docket Number	05432/100M029-US2

177.	Test results H. Lundbeck A/S faxed to EPO 17.01.02	
178.	Letter from Hoffman Eitle to EPO 6 May 2002, European Patent App. No. 01 909 568.6-2117	
179.	Betænkning/office action from DK PTO of 15 October 2001, PATENT-OG VAREMÆRKESTYRELSSEN, Leila Nielsen	
180.	H. Lundbeck A/S amendments, EP-A-347 066, with letter from S. J. Wilkinson (June 17, 1994)	
181.	H. Lundbeck A/S reply to official action from EPO - dated 17 January 2002, EP application no. 01 909 568.6-2117, John Meidahl Petersen	
182.	Alkaloid Chemistry, Budapest, Ungarn (May 10, 2003 ), Expert Opinion of Prof. Dr. Csaba Szantay re: Reproduction of Example 3 of the EP 347066 B1 European patent	
183.	Stockholm Tingsrätts decision (May 31, 2002), PROTOKOLL	
184.	EPO examination report (January 10, 2002), Application No. 01 909 568.6-2117	
185.	Writ for Registration, Van Mastrigt & Partners, 3/22/03	
186.	Decision from Stockholm Tingsret dated 5 June 2002, PROTOKOLL	
187.	Report re: Dutch patents NL 1016435 and NL 1017413	
188.	Correspondence [with the Finnish Patent Office] re patent in suit, PATENT-OCH REGISTERSTYRELSEN, FORELAGGANDE, November 10, 2001	
189.	Minutes from EPO oral hearing 24 May 2002 and approved corrections	
190.	Telephone Conference Report from EPO re: Appl. No. 01 909 568.6 (February 26, 2002)	
191.	Återkallelse av ansökan PCT/EP00/06426; Notarbartolo & Gervasi	
192.	Lundbecks anförande i rättegången i Nederländerna mot Tiefenbacher och GEAs moderbolag Hexal Pharma	
193.	Lundbecks svaromål i mål T 7589-02, 2002-05-24, SANDART & PARTNERS ADVOKATBYRA	
194.	Organikum Organisch-Chemisches Grundpraktikum (1975, 14th edition )	

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